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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/709,997	06/11/2004	Mark A. Johanson	22956-302 (MIT-169CON)	3996
21125 7590 07/16/2008 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			EXAMINER WOO, JULIAN W	
			ART UNIT 3773	PAPER NUMBER
			NOTIFICATION DATE 07/16/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary	Application No. 10/709,997	Applicant(s) JOHANSON ET AL.	
	Examiner Julian W. Woo	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to base claim 1, a sheath is said to be "cutting bone" (instead of "for cutting bone"). It is not certain whether bone, which is an unpatentable part of the human body, is being claimed as a structural part of the invention.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1 and 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable Simon (5,346,497) in view of Hallac (3,605,721). Simon discloses the invention substantially as claimed. Simon discloses, at least in figures 3-13, an apparatus including a tube with an inner bore (3), a distal end having a cutting edge, and at least one recess (6) adjacent the distal end that extends at least part way from the an inner surface of the tube to an outer surface of the tube; and a sheath (2) disposed around the tube and including a tooth (18) extending towards the inner bore in a direction substantially orthogonal to the cutting edge. However, Simon does not disclose a tube with at least one recess or aperture spaced apart from the distal end and extending at least part way from an inner surface of the tube to an outer surface of the tube or beginning a predetermined distance away from the distal end of the tube. Hallac teaches, at least in figures 4, 5, and 8 and in col. 4, lines 25-36; an apparatus for harvesting tissue plugs, where the apparatus includes a tube with cutting edges and a plurality of recesses or apertures (e.g., 52 or 54) each extending from an inner surface of the tube to an outer surface of the tube and running towards the proximal end of the tube and beginning a predetermined distance away from the distal end of the tube. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Hallac, to modify the tube in the apparatus of Simon, so that it has a plurality of recesses or apertures adjacent the distal end of the tube. Such recesses or apertures would allow the capturing of tissue to the depth of penetration of the tube within the tissue.

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5. Claims 2, 6, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simon (5,346,497) in view of Hallac (3,605,721), and further in view of Stavropoulos et al. (4,142,517). Simon in view of Hallac discloses the invention substantially as claimed, but does not disclose a sheath including one or more markings or a plurality of markings on an outer surface thereof, the one or more markings corresponding to an amount that the sheath is inserted into bone tissue or a plurality of markings for indicating an insertion depth of the sheath into bone. Simon in view of Hallac also does not disclose that the tube has a handle, nor does Simon in view of Hallac disclose that the tube has a mating element at its proximal end, and that the sheath includes a connector for removable engagement with the mating element. Stavropoulos et al. teach, at least in figures 5 and 6 and in col. 1, line 7 to col. 2, line 51; a sheath (18) mated to a tubular apparatus (40) for harvesting bone plugs, where the sheath includes markings (22) corresponding to an amount that the sheath is inserted into bone tissue. Stavropoulos et al. also teach a tube (40) with a handle (54) and a mating element (46) and a sheath (18) with a connector (46) for removable engagement with the mating element. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Stavropoulos et al., to include a sheath with markings in the device of Simon in view of Hallac. Such a sheath would allow a measurement of and a limit to the depth of insertion the tube within a patient's body, and would thus safety prevent overextension of the tube into the patient's body. It would also be obvious to include a handle and a mating element in the tube of Simon in view of Hallac and a connector with the sheath of Simon in view of Hallac. A handle

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would allow the rotation of the tube manually or by a motor; while a mating element and a connector would allow the depth of tube penetration into tissue to be measured and controlled.

6. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Simon (5,346,497) in view of Hallac (3,605,721), and further in view of Torrie et al. (6,358,253). Simon in view of Hallac discloses the invention substantially as claimed. Simon in view of Hallac discloses an apparatus for harvesting tissue, but does not disclose an apparatus including a bone plug formed from articular cartilage and underlying bone tissue. Torrie et al. teach, at least in col. 7, line 39 to col. 8, line 21, an apparatus including a harvested bone plug (87) formed from articular cartilage (86) and underlying bone tissue. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Torrie et al., to include a bone plug formed from articular cartilage and underlying bone tissue with the apparatus of Simon in view of Hallac. Such a bone plug would allow the repair and replacement of bone that is covered with damaged cartilage.

Response to Amendment

7. Applicant's arguments with respect to claims 1-7 and 28 have been considered but are not persuasive. Regarding arguments regarding the rejection based on Simon and Stavropoulos: Simon does not limit the use of the device to cataract surgery. Simon discloses, for example, in col. 1, lines 11-20; that the device is for "performing surgery on various parts of the body, such as menisci." Thus, one of ordinary skill would combine Simon with Stavropoulos in order to have an advantage or benefit in

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measuring insertion depth of the device into thicker tissues (i.e., thicker relative to an eye surface) such as bone or menisci.

Regarding arguments regarding the rejection based on the Hallac reference: Because Simon's device is applicable for the cutting of tissues other than eye tissue, one of ordinary skill in the art would combine Simon with Hallac in order to have an advantage or benefit in capturing of tissue to the depth of penetration of the tube within thicker tissues as mentioned above.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773

July 10, 2008